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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,478	06/23/2005	Nils Erik Holmertz	19200-000049/US	2985
30/593 7590 05/04/2009 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195				
EXAMINER NGUYEN, TRINH T				
ART UNIT		PAPER NUMBER		
3644				
MAIL DATE		DELIVERY MODE		
05/04/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,478

Applicant(s)

HOLMERTZ ET AL.

Examiner

Trinh T. Nguyen

Art Unit

3644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Amend dated 1/30/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-27, 32 and 35-38 is/are rejected.
- 7) ☒ Claim(s) 28-31, 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-23,25-27,32, and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In this case, there is no support in the original disclosure for the subject matter (i.e. "about 1000 or more") as claimed in claims 1,18, and 33. It is noted that paragraph [0042] of the specification as published only mentioned "By recording a large number, e.g. thousands, of images..." but it does not mention "about 1000 or more".

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-23,25-27,32, and 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Since there is no support in the original disclosure regarding the subject matter (i.e. "about 1000 or more") as claimed in claims 1,18, and 33, it is not clear what is being claimed regarding the term "about" and "more".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6,8-10,13, 15-23, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakes (US6694830) in view of Hansen et al. (US6731100).

For claims 1,17, and 18 (as best understood), Hakes discloses a method for sampling/testing for mastitis (which would include the somatic cell count in milk) in milking animals wherein the method includes the step of flowing at least a portion of the milk as obtained during said milking of said milking animal through a measuring chamber (50).

Hakes lacks to mention the steps of: illuminating milk that flows through said measuring chamber; repeatedly recording about 1000 or more two-dimensional digital images of illuminated milk that flows through said measuring chamber, said two-dimensional digital images being recorded through a magnification lens system; and determining a somatic cell or fat droplet count score from said two-dimensional images by means of digital image processing.

Hansen et al. teach a similar method as that of Hakes wherein Hansen et al.'s method includes the steps of: illuminating milk that flows through said measuring chamber; repeatedly recording two-dimensional digital images of illuminated milk that

flows through said measuring chamber, said two-dimensional digital images being recorded through a magnification lens system; and determining a somatic cell or fat droplet count score from said two-dimensional images by means of digital image processing (see lines 30-57 of col. 3, lines 1-15 of col. 4, lines 5-35 of col. 5, lines 63-67 of col. 5, lines 1-3 of col. 6, lines 44-65 of col. 6, lines 38-45 of col. 7, lines 50-63 of col. 11, lines 30-50 of col. 32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes so as to include the steps of "illuminating...", "repeatedly recording...", and "determining...", since to do so would merely replace one old and well known method of sampling/testing mastitis in milk (as taught by the sampling device 50 of Hakes) with another art equivalent old and well known method of sampling/testing mastitis in milk (as taught by the sample compartment of Hansen et al. (see Abstract)).

With respect to the limitation of "about 1000 or more two-dimensional digital images" as claimed in claims 1 and 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. (emphasis on Hansen et al.) so as to include about 1000 or more two-dimensional digital images, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art so that the images of illuminated milk can be recorded more precisely. Also, since applicant did not provide a reason and/or showing any criticality as to why the two-dimensional digital images has to be recorded at the specified requirement, i.e., about 1000 or more (note that paragraph

[0042] of the specification as published only indicated "By recording a large number, e.g. thousands, of images..." and not "about 1000 or more"), it is believe that through trial and error during the sampling/testing procedure that one comes up with a desirable number of two-dimensional digital images to meet the design criteria of having the images of illuminated milk recorded more precisely.

For claims 2 and 19, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. (emphasis on Hakes) to include the measuring chamber is free from toxic additives so as to eliminate and/or prevent the sampling/testing milk from contamination and thus result in an error result/assessment.

For claims 3 and 20, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. (emphasis on Hakes) to include at least portion of the milk flowed through said measuring chamber is pure natural milk, optionally mixed with air, but free from any chemical additives so as to eliminate and/or prevent the sampling/testing milk from contamination and thus result in an error result/assessment.

For claims 4,17 and 21, Hakes as modified by Hansen et al. discloses most of the claimed invention except for mentioning that the spatial resolution is better than about 5 microns in said two-dimensional digital images. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. so as to include the spatial resolution is better than about 5 microns, since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Also, since applicant did not provide a reason and/or showing any criticality as to why the spatial resolution has to be better than about 5 microns, it is believe that through trial and error during the sampling/testing procedure that one comes up with a desirable spatial resolution to meet the design criteria for counting cells.

For claims 5 and 22, Hakes as modified by Hansen et al. discloses most of the claimed invention except for mentioning that the measuring chamber has a dimension smaller than about 100 microns in a direction parallel with the optical axis of said lens system during said repeated recordings. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. so as to include the measuring chamber has a dimension smaller than about 100 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Also, since applicant did not provide a reason and/or showing any criticality as to why the dimension of the measuring chamber has to be smaller than about 100 microns, it is believe that through trial and error during the sampling/testing procedure that one comes up with a desirable dimension for the measuring chamber to meet the design criteria.

For claims 6 and 23, it is inherently that the digital image processing of Hakes as modified by Hansen et al. (emphasis on Hansen et al.) includes the analysis of number, shape, size, structure, density and/or composition of particles found in each image as

revealed by the reflection by at least one of the reflection and transmission properties of the particles recorded spatially resolved by said camera system.

For claim 8, Hakes as modified by Hansen et al. (emphasis on Hakes) further disclose said at least portion of said milk, which is flowed through said measuring chamber, is lead away from a milk line (11) of a milking machine used to collect the milk as obtained during said milking of said milking animal.

For claim 9, Hakes as modified by Hansen et al. (emphasis on Hakes) further disclose said at least portion of said milk, which is lead away from said milk line (11), is brought back to said milk line or brought to a milk collecting container (note that the fluid collection line 15 in Figure 1 will bring milk to a some sort of milk collecting container), after having been flowed through said measuring chamber.

For claim 10, Hakes as modified by Hansen et al. (emphasis on Hakes) further disclose said at least portion of said milk is flowed through said measuring chamber (50) within a milk line (11) of a milking machine used to collect the milk as obtained during said milking of said milking animal.

For claim 13, it is inherently that the somatic cell or fat droplet count score of Hakes as modified by Hansen et al. (emphasis on Hansen et al.) is a count score of white cells.

For claim 15, it is inherently that the content of fat of Hakes as modified by Hansen et al. (emphasis on Hansen et al.) is estimated from said two-dimensional images by means of said digital imaging processing.

For claim 16, it is inherently that the content of fat of Hakes as modified by Hansen et al. (emphasis on Hansen et al.) is estimated from number and size of fat droplets in said two-dimensional images.

For claims 35 and 36, Hakes as modified by Hansen et al. discloses most of the claimed invention except for mentioning that a spatial resolution in the digital images of about 5 microns or less. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. so as to include the spatial resolution in the digital images of about 5 microns or less, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Also, since applicant did not provide a reason and/or showing any criticality as to why the spatial resolution has to be about 5 microns or less, it is believe that through trial and error during the sampling/testing procedure that one comes up with a desirable spatial resolution to meet the design criteria.

For claims 37 and 38, since the method of Hakes as modified by Hansen et al. (emphasis on Hansen et al.) teach the assessment of somatic cells in a milk or milk product, it is inherently that the step of analyzing at least one of shape, size, structure, density, and composition of the somatic cells would include in the assessment process.

7. Claims 11,12,14,25-27, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakes (US6694830) in view of Hansen et al. (US6731100), and further in view of van der Lely et al. (US6367416).

For claims 11,12, and 25, Hakes as modified by Hansen et al. (emphasis on Hakes) further disclose said milking of said milking animal is performed by a milking system, which comprises a plurality of teat cups (20), each of which being connected to a respective milk line, which milk lines in turn are connected to a container (30) via a claw and a single milk line, wherein, during milking of the teats of said milking animal, said plurality of teat cups are attached to the teats of the milking animal and vacuum is supplied to said container to draw milk through said milk lines, said claw, said single milk line and into said container, wherein said milk is drawn in separate milk lines all the way to said container (30) (see lines 10-50 of col. 6).

Hakes as modified by Hansen et al. (emphasis on Hakes) lacks to mention an automated or semi-automated milking system.

van der Lely et al. teach a similar method as that of Hakes as modified by Hansen et al. wherein van der Lely et al.'s method includes the use of a fully automated milking system (see Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. so as to include the use of a fully automated milking system, in a similar manner as taught in van der Lely et al., so that the milking system can be operated independently without an operator and thus reduce the overall cost of operation.

For claims 14, Hakes as modified by Hansen et al., and further modified by van der Lely et al. (emphasis on Hakes) further disclose said container is provided with a plurality of milk output lines (milk line from 30 to 16 and milk line from 30 to 50 in Figure

1); and said milk drawn through the milk lines and into said container is output through one of said plurality of milk output lines depending on said somatic cell or fat droplet count score.

For claims 26, Hakes as modified by Hansen et al., and further modified by van der Lely et al. (emphasis on Hansen et al.) further disclose said measuring chamber is defined by a light transparent plate mounted in a wall of said one of said milk lines, through which said two-dimensional camera system is adapted to record said two-dimensional images; and an oppositely located substantially fiat and parallel surface (see lines 30-57 of col. 3).

For claims 27, Hakes as modified by Hansen et al., and further modified by van der Lely et al. (emphasis on Hansen et al.) further disclose said measuring chamber is open in directions being parallel with said light transparent plate and said substantially fiat surface, and orthogonal to a general direction of the flow of said at least portion of said milk (see lines 30-45 of col. 3).

For claims 32, Hakes as modified by Hansen et al., and further modified by van der Lely et al. (emphasis on Hansen et al.) further disclose each of said milk lines is provided with a measuring chamber, through which a portion of the milk drawn through the respective milk line is passed; said light source system is adapted to illuminate milk that flows through each of said measuring chambers; said two-dimensional camera system is adapted to repeatedly record two-dimensional digital images of illuminated milk that flows through each of said measuring chambers; and said digital image

processing system is adapted to determine a somatic cell or fat droplet count score for milk drawn through each of said milk lines from said two-dimensional images.

Allowable Subject Matter

8. Claims 28-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. Claim 33 is would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments filed 1/30/09 have been fully considered but they are not persuasive.
11. Regarding to Applicant's argument with respect to the rejection under 35 U.S.C. 112, first paragraph, it is noted that there is no support in the original disclosure for the subject matter (i.e. "about 1000 or more") as claimed in claims 1,18, and 33. It is noted that paragraph [0042] of the specification as published only mentioned "By recording a large number, e.g. thousands, of images..." but it does not mention "about 1000 or more".
12. Applicant argues that Hansen et al. does not teach the limitation of "about 1000 or more" as claimed in claims 1,18, and 33, Applicant's argument is acknowledged. However, it is noted that Hansen et al. teach a similar method as that of Hakes wherein Hansen et al.'s method includes the steps of: illuminating milk that flows through said

measuring chamber; repeatedly recording two-dimensional digital images of illuminated milk that flows through said measuring chamber, said two-dimensional digital images being recorded through a magnification lens system; and determining a somatic cell or fat droplet count score from said two-dimensional images by means of digital image processing (see lines 30-57 of col. 3, lines 1-15 of col. 4, lines 5-35 of col. 5, lines 63-67 of col. 5, lines 1-3 of col. 6, lines 44-65 of col. 6, lines 38-45 of col. 7, lines 50-63 of col. 11, lines 30-50 of col. 32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes so as to include the steps of "illuminating...", "repeatedly recording...", and "determining...", since to do so would merely replace one old and well known method of sampling/testing mastitis in milk (as taught by the sampling device 50 of Hakes) with another art equivalent old and well known method of sampling/testing mastitis in milk (as taught by the sample compartment of Hansen et al. (see Abstract)). Furthermore, with respect to the limitation of "about 1000 or more two-dimensional digital images" as claimed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Hakes as modified by Hansen et al. (emphasis on Hansen et al.) so as to include about 1000 or more two-dimensional digital images, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art so that the images of illuminated milk can be recorded more precisely. Also, since applicant did not provide a reason and/or showing any criticality as to why the two-dimensional digital images has to be recorded at the specified

requirement, i.e., about 1000 or more (note that paragraph [0042] of the specification as published only indicated "By recording a large number, e.g. thousands, of images..." and not "about 1000 or more"), it is believe that through trial and error during the sampling/testing procedure that one comes up with a desirable number of two-dimensional digital images to meet the design criteria of having the images of illuminated milk recorded more precisely.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Trinh T. Nguyen whose telephone number is (571) 272-6906. The examiner can normally be reached on M-F (1:30 P.M to 10:00 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Mansen can be reached on (571) 272-6608. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Trinh T Nguyen/
Primary Examiner, Art Unit 3644
5/3/09